SEP 6 2002

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511

K022796

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: AUG 19 2002

TRADE NAME: CERCON® CERAM S PORCELAIN

CLASSIFICATION NAME: Porcelain Powder for Clinical Use (872.6660)

PREDICATE DEVICES: Cercon® Ceram K011333

DEVICE DESCRIPTION: CERCON® CERAM S PORCELAIN is a dental ceramic veneering material developed for veneering Cercon zirconia or an equivalent zirconium oxide substructure for fixed prosthodontics devices that include both anterior and posterior crowns/bridges.

The CERCON® CERAM S PORCELAIN System consists of Dentin/Transparent/Incisal, Liner/Opaque, Shoulder, and Correction/Glaze/Stain Porcelains. The final restoration matches more shades than the predicate device.

INTENDED USE: CERCON® CERAM S PORCELAIN is for use on zirconia (zirconium oxide) in single tooth or bridge type restorations. Applications include both anterior and posterior locations.

TECHNOLOGICAL CHARACTERISTICS: CERCON® CERAM S PORCELAIN represents a modification to Cercon® Ceram (K011333). Minor changes have been made in the device's formulation.

All of the components have been used in legally marketed devices. CERCON® CERAM S PORCELAIN was evaluated and passed biocompatibility testing for cytotoxicity.

We believe that the prior use of the components in legally marketed devices, the similarity in the formulations between the modified device and the marketed device, and the data provided regarding the modifications to the marketed device support the safety and effectiveness of CERCON® CERAM S PORCELAIN for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 6 2002

Mr. P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K022796
Trade/Device Name: Cercon® Ceram S
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: August 19, 2002
Received: August 23, 2002

Dear Mr. Lehn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K022796

Device Name: **CERCON® CERAM S PORCELAIN**

Indications for Use:

Designed for use on zirconia (zirconium oxide) in single tooth or bridge type restorations. Applications include both anterior and posterior locations.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022796